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REVIEW

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How well does vaccine literacy predict intention to vaccinate and vaccination status? A systematic review and meta-analysis

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ABSTRACT

This review quantified the association of vaccine literacy (VL) and vaccination intention and status. PubMed, Scopus, and Web of Science were searched. Any study, published until December 2022, that investigated the associations of interest were eligible. For each outcome, articles were grouped according to the vaccine administrated and results were narratively synthesized. Inverse-variance random-effect models were used to compare standardized mean values in VL domain(s) between the two groups: individuals willing vs. unwilling to get vaccinated, and individuals vaccinated vs. unvaccinated. This review of 18 studies shows that VL strongly predicts the vaccination intention while its association with vaccination status is attenuated and barely significant, suggesting that other factors influence the actual vaccination uptake. However, given the scarce evidence available, the heterogeneity in the methods applied and some limitations of the studies included, further research should be conducted to confirm the role of VL in the vaccination decision-making process.

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Introduction

Immunization is considered a key component of primary health care and an indisputable human right.[1] Vaccines help prevent and control infectious-disease outbreaks, as well as antimicrobial resistance,[2–4] and they also have a critical role in cancer prevention.[5–7] New vaccines are currently available or in the pipeline for long-standing deadly diseases, including malaria and tuberculosis,[8] while research on therapeutic vaccination is opening up new horizons in medicine.[9] Despite the undeniable importance of vaccines, the COVID-19 pandemic triggered widespread disinformation on vaccination, undermining the understanding and acceptance of science and health policies,[10] including vaccine adherence.[11] Alongside, structural barriers, such as the geographical distance to healthcare centers, limited service hours but also reduced availability of the health workforce,[12,13] caused an unprecedented and sustained decline in immunization coverage, leaving 25 million children unvaccinated or under-vaccinated for routine immunizations in 2021.[14]

In this context, several factors have been investigated by researchers to assess their influence on vaccination behavior, including vaccine literacy (VL).[15–17] Vaccine literacy, a form of health literacy (HL), is a relatively new concept.[18] Although a single and unambiguous definition is still lacking, the Health Literacy Survey Consortium defines it as "individuals' knowledge, motivation, and skills to find, understand, and evaluate immunization-related information in order to make adequate immunization decisions".[19] Similarly to HL, it is affected by several factors including socio-economic status and level of education. Accordingly, VL has been proposed to affect vaccination acceptance and therefore could be a means of tackling vaccine hesitancy.[20]

Several researchers have studied VL in relation to vaccination behavior,[21] but despite the growing number of studies on this topic,[21,22] a few limitations have contributed to the poor generalizability of the results, including small sample sizes, narrowly defined target populations, and differences in the vaccines investigated and the scales or sub-scales used for VL measurement.[18,21,23] Furthermore, the evidence presented has largely been inconclusive, with no clear relationship between VL and vaccination behavior emerging to date.[21,22] Therefore, we conducted a systematic review and meta-analysis to synthesize the evidence on this topic and provide a quantitative estimate of the association between VL and vaccination behavior, considering both intention and vaccination status. The results may contribute to a better understanding of VL as a potential predictor of vaccination adherence and may point toward more targeted strategies for implementing vaccination adherence.

Materials and methods

This study was performed according to the Cochrane Handbook for Systematic Reviews and the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) statement.[24,25] The review protocol was registered at PROSPERO (identifier CRD42022381807). Since primary data collection was not performed, informed consent was not required, and the protocol was not submitted for institutional review board approval.

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Search strategy and study selection

We searched the bibliographic databases PubMed, Web of Science and Scopus using the following search terms: ("vaccin*" AND "literacy") OR ("vaccine literacy"). The string adaptation to fit the search criteria of each database is shown in Supplementary Table S1. The search was conducted among records published from database inception to 28 December 2022. No language or date restrictions were applied. After the removal of duplicate records, three reviewers independently screened the title and abstract of all records retrieved. Studies that did not meet the inclusion criteria were excluded and three researchers examined the full texts of potentially relevant articles. Disagreements were resolved through discussion and reasons for exclusion were recorded.

Inclusion and exclusion criteria

We included studies that i) reported in English or Italian, based our coauthor language abilities; ii) had an observational design (i.e., cohort, case-control, cross-sectional); iii) investigated at least one domain of general or vaccine-specific VL (e.g., COVID-19 VL); and iv) provided raw data, unadjusted or adjusted estimates of the association between VL and vaccination intention and/or status in any population(s). Any statistical analysis was considered eligible. Articles that analyzed vaccination acceptance (i.e., a combination of vaccination intention and status) or in which data or estimates of the associations of interest were not described or retrievable were excluded.

Data collection and quality assessment

For each record included, three reviewers independently extracted the following information using a standardized data abstraction form: first author, year of publication, country, study design, main characteristics (age, ethnicity, recruitment process, and number of participants) of target population, type of vaccine (e.g., against SARS-CoV-2, HPV, etc.), tools used to assess VL and the domain(s) investigated, outcome definition and measurement, statistical analysis, main findings, and adjustment factors (if applicable). The sample size was categorized in low (<100 participants), medium (101–1000 participants), large (1001–1000 participants) and very large (>10000 participants). Quality assessment of the articles included was carried out by three independent authors, using an adapted version for cross-sectional studies of the Newcastle-Ottawa scale.[26] Articles were considered of high quality when the total score was ≥7, of fair quality if the score was ≥5 and <7, and of poor quality if the score was lower than 5.[27] Discrepancies were resolved through discussion and achievement of consensus.

Data synthesis and statistical analysis

Two main outcomes were investigated: intention to be vaccinated and vaccination status. Then, for each outcome, articles were grouped according to the type of vaccine and a narrative synthesis of the main findings was performed. In addition, inverse-variance random-effect meta-analyses were conducted to pool standardized mean differences (SMD) in VL scores between two groups: for the vaccination intention outcome, individuals that were willing to be or were sure about being vaccinated vs. individuals that were unwilling or unsure; for the vaccination status outcome, individuals that were vaccinated vs. those that were unvaccinated. As for the VL domains, since they investigate different capabilities of individuals, we considered separately overall VL, functional VL, interactive VL, critical VL and interactive/critical VL. Indeed, according to Biasio et al., functional VL regards language capabilities, encompassing the semantic system, while interactive/critical domains focus on cognitive efforts such as problem solving and decision making.[28] Studies that did not report the mean levels of these VL domains in each group, or in which the mean values were not retrievable, were excluded from the meta-analysis. The Cochrane χ^2 test and the I^2 metric were used to test for heterogeneity.[29] Heterogeneity was considered statistically significant at p-value <.05, and substantial heterogeneity was defined as $I^2 > 50\%$. For both outcomes, whenever possible, we stratified studies by a few variables that could influence heterogeneity: type of vaccine considered (i.e., SARS-CoV-2 booster dose, SARS-CoV-2 primary cycle, or influenza), by VL tool used (i.e., Adult Vaccination Health Literacy in Italian [HLVa-IT], COVID-19 Vaccine Literacy Scale [COVID-19 VLS], or others), and by target population (i.e., general population, with no particular features, or specific populations). Since one study[30] reported data on the willingness to receive two types of vaccine separately (i.e., SARS-CoV-2 and influenza) but in the same population, and we did not want to lose any information, we first pooled the data on SARS-CoV-2, while the data on influenza vaccination was used instead in a sensitivity analysis. In addition, since the number of studies retrieved was always lower than 10 within each analysis, we followed the Cochrane guidelines[25] such that the small study effect, potentially caused by publication bias, was not assessed. For a similar reason, given the limited availability of studies within each outcome, meta-regression analyses were not performed. A p-value < .05 was considered statistically significant. All analyses and graphs were performed using Review Manager (RevMan, The Cochrane Collaboration, 2020), version 5.4, and GraphPad Prism (GraphPad Software, San Diego, California USA), version 9.0.

Results

Overall, 3326 records were identified by database searching (Figure 1). After duplicate removal and screening by title and abstract, 61 articles were assessed for eligibility, of which 43 were excluded with reasons at the full-text analysis stage, providing a total of 18 articles for inclusion in the systematic review: of these, nine studies (50.0%) investigated intention to vaccinate,[31–39] four studies (22.2%) explored vaccination status[28,40–42] and five studies (27.8%) considered both outcomes separately.[30,43–46] For the meta-analysis, 10 articles (55.6%) provided estimates that were ultimately pooled.

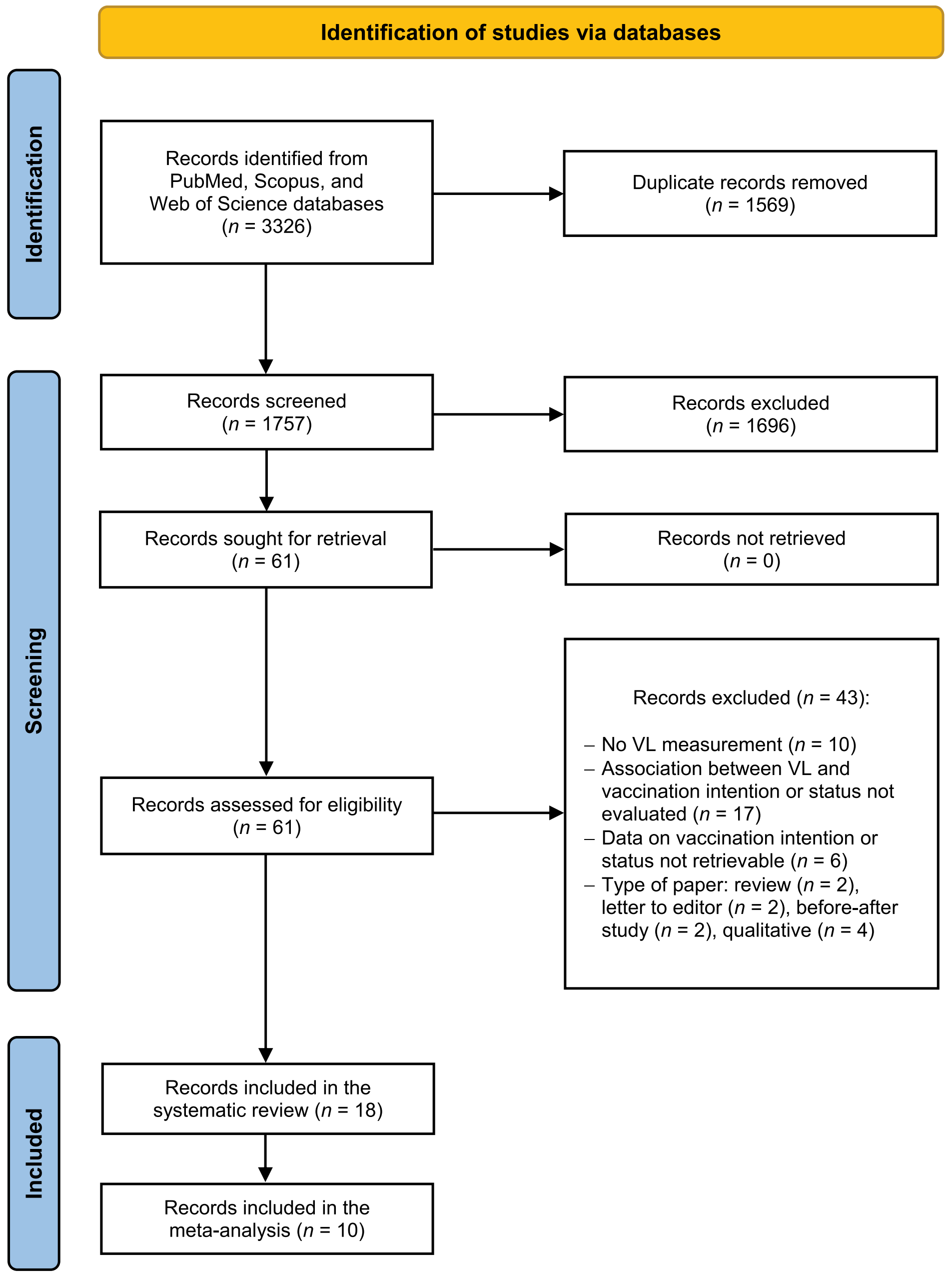


Figure 1. PRISMA flow diagram of the review process. VL: vaccine literacy.

Characteristics of the studies included in the systematic review

Studies investigating vaccination intention only

All nine studies that only investigated vaccination intention were published in 2021[31–35] or 2022[36–39] and had a cross-sectional design[31–39] (Table 1). Two were conducted in the United States,[35,37] two in Saudi Arabia,[31,38] one in Israel,[32] one in Croatia,[33] one in Bangladesh,[34] one in India[36] and one in Japan.[39] The general population was investigated in the majority of studies,[33–38] while in two cases the sample was enrolled from COVID-19 booster-hesitant individuals.[36,37] One study recruited parents of adolescent children[32] whereas in two articles university students were targeted,[31,39] with one restricting the investigation to nursing students.[31] In all but two studies the recruitment process was performed online using social networks[32–34,38] or commercial panels.[35–37] A large sample size (i.e., more than 1000) was enrolled in four studies.[31,33,35,38] All but one study investigated the SARS-CoV-2 vaccine[31–38] (primary or booster vaccination), with the exception focusing on human papillomavirus (HPV) vaccine.[39] Quality was judged to be high in six studies[31,34–38] and fair in the remaining three articles,[32,33,39] in which the main deficits were issues with the sample used (insufficiently representative; no justification for sample size) and a lack of data on the comparability between survey participants and non-participants (Supplementary Table S2).

Table 1. Characteristics of the studies included in the systematic review.

First author, year	Country	Study design	Target population (sample size)	Vaccination	Quality
Studies investigating vaccination intention only					
Alshehry, 2021	Saudi Arabia	CS	Nursing students recruited in universities (*N* = 1170)	SARS-CoV-2	7
Gendler, 2021 #	Israel	CS	Parents of children aged 12–15 years recruited online using social networks (*N* = 520)	SARS-CoV-2	5
Gusar, 2021	Croatia	CS	General population aged ≥18 years recruited online using social networks (*N* = 1227)	SARS-CoV-2	5
Nath, 2021	Bangladesh	CS	General population aged 18–30 years recruited online using social networks (*N* = 343)	SARS-CoV-2	9
Yadete, 2021 #	United States	CS	General population aged ≥18 years recruited online using commercial panels (*N* = 2138)	SARS-CoV-2	8
Achrekar, 2022 #	India	CS	General population aged ≥18 years recruited online using commercial panels (*N* = 687)	SARS-CoV-2	8
Batra, 2022 #	United States	CS	General population aged ≥18 years recruited online using commercial panels (*N* = 501)	SARS-CoV-2	8
Gutierrez, 2022 #	Saudi Arabia	CS	General population aged ≥18 years recruited online using social networks (*N* = 2514)	SARS-CoV-2	7
Suzuki, 2022	Japan	CS	University male (*N* = 65) and female (*N* = 57) students aged 18–35 years recruited in four universities using campus website/course of study e-bulletin boards	HPV	5
Studies investigating vaccination status only					
Lee, 2015	United States	CS	White (*N* = 1929) and AAPI (*N* = 341) female undergraduate students aged 18–25 years recruited in a university using institutional e-mail address (*N* = 1929)	HPV	8
Biasio, 2020 (A)	Italy	CS	Individuals aged ≥65 years attending an appointment in a local health unit (*N* = 128)	IPT	7
Engelbrecht, 2022	South Africa	CS	General population ≥18 years recruited online using social networks (*N* = 10466)	SARS-CoV-2	7
Yilmaz, 2022 #	Turkey	CS	Nursing students recruited in a university (*N* = 391)	SARS-CoV-2	6
Studies investigating both vaccination intention and status					
Biasio, 2020 (B) #	Italy	CS	General population including representatives of citizens, patients and healthcare workers recruited from e-mail list of a medical foundation and using social networks (*N* = 885)	SARS-CoV-2 - intention Influenza – intention and status	5
Krishnamurthy, 2022 #	Barbados	CS	Healthcare professionals recruited in a hospital using institutional e-mail address (*N* = 343)	SARS-CoV-2 - intention Influenza – status	5
Kittipimpanon, 2022	Thailand	CS	Older adults aged ≥60 years recruited online using social networks (*N* = 224)	SARS-CoV-2 - intention and status	7
Correa-Rodriguez, 2022 #	Spain	CS	Patients with a systemic autoimmune disease aged ≥18 years recruited from an online association using a patient association Facebook page (*N* = 319)	SARS-CoV-2 - intention Influenza – status	5
Li, 2022	China	CS	General population ≥18 years recruited online (*N* = 362)	SARS-CoV-2 - intention and status	6

AAPI: AAPI: Asian American and Pacific Islander; CS: cross-sectional; HPV: human papilloma virus; IPT: influenza, *Pneumococcus* & tetanus.
#:studies included in the meta-analysis.

Studies investigating vaccination status only

Of the four studies that only explored vaccination status, one was published in 2015,[40] one in 2020[28] and two in 2022[41,42] (Table 1). One study was conducted in Turkey,[42] one in the United States,[40] one in Italy[28] and one in South Africa.[41] All studies had a cross-sectional design.[28,40–42] The target population was the general population in two articles, enrolled either online[41] or in healthcare settings,[28] and comprised university students in the two remaining cases,[40,42] with one study focusing on nursing science.[42] The ethnicity of the participants was specified in only one article.[40]

The sample was very large (i.e., more than 10,000 participants) in only one study[41]; the other studies were large (i.e., more than 1000 people)[40] or medium (i.e., more than 100 people)[28,42] in scale. Two articles looked at SARS-CoV-2 vaccine,[41,42] one investigated HPV vaccination[40] and one considered combined vaccination against influenza, *Pneumococcus* and tetanus (IPT).[28] All studies were judged of high or fair quality. A lack of data comparing the characteristics between survey participants and non-participants was the main deficit (Supplementary Table S2).

Studies investigating both vaccination intention and status

The five studies that investigated both vaccination intention and status were published in 2020[30] or 2022[43–46] (Table 1). All studies had a cross-sectional design.[30,43–46] In each case, a single study was conducted in Italy,[30] Barbados,[43] Thailand,[44] Spain[45] and China.[46] The population enrolled varied: in two cases the sample included individuals from a medical foundation[30] or patients with autoimmune diseases[45]; one recruited healthcare professionals,[43] while two targeted the general population either aged ≥18 years[46] or aged ≥60 years.[44] The recruitment process always took place online, using social networks[44–46] or e-mail addresses.[30,43] The sample size was deemed to be medium in all studies considered (i.e., more than 100).[30,43–46] Vaccination against SARS-CoV-2 was explored in all articles,[30,43–46] three of which also investigated flu vaccination.[30,43,45] Quality was fair in all but one study,[44] which had no justification of the sample size and lacked comparability between responders and non-responders (Supplementary Table S2).

Main findings

Association between VL and vaccination intention

Systematic review. Out of 13 studies that investigated the participants' intention to be vaccinated against SARS-CoV-2, seven used the original or an adapted version of the HLVa-IT tool,[30,31,35–37,45,46] five adopted the COVID-19 VLS questionnaire,[32–34,38,44] whereas an ad hoc questionnaire was developed in the remaining case[43] (Table 2). Vaccine literacy was reported as a scale in all studies included[30–38,43–46]: two studies provided data both on some VL domains and on the overall VL score,[32,46] seven articles[30,31,33,35,38,43,45] analyzed VL domains only (i.e., functional, interactive and critical), while in four cases[34–36,44] only an overall VL score was provided. Vaccination intention was explored using one[30,31,33-38,43–46] or two self-reported questions.[32] Participant answers were dichotomized in the majority of studies,[30,32,33,35–38,43,45,46] but were divided into three categories in two cases,[31,44] whereas only one study expressed the outcome as a mean score of agreement to vaccination.[34] Four out of thirteen articles performed regression models as the main method of analysis,[31,34,36,37] while the others used univariable analyses, comparing mean or median values between groups.[30,32,33,35,38,43–46.] Results were heterogeneous: for the univariable analyses, all VL domains seemed to influence the intention to have primary or booster vaccination in six studies,[33,35–37,43,44] but the association remained significant in only one[37] out of the two studies, which also performed a multivariable analysis after restricting the sample to hesitant participants.[36,37] Conversely, none of the VL levels seemed to influence vaccination intention in the other four univariable analyses,[32,34,45,46] even in the two studies that adjusted the analysis for socio-demographic characteristics or COVID-19 experience, beliefs and attitudes.[31,34] Lastly, inconclusive findings were reported by Biasio et al. and Gutierrez et al., in which higher interactive/critical VL levels were found to be positively associated with vaccination intention in unadjusted analyses, whereas the functional domain was not.[30,38]

Influenza vaccination was evaluated in one study.[30] VL was measured with an adapted version of the HLVa-IT tool and its levels were used as a mean score, after considering separately functional and interactive/critical domains. Vaccination intention was investigated with one question on the willingness to obtain flu vaccination in the current year, and the answers were dichotomized. In a univariable analysis, a significant association was found between higher functional and interactive/critical VL levels and the intention to be vaccinated.

One study explored HPV vaccination intention in male and female university students using an ad hoc questionnaire that provided a mean score of overall VL levels.[39] The outcome was calculated as time to receive the HPV vaccination and answers were collapsed into two categories, i.e., immediately to within three years vs. no intention to get vaccinated. Higher overall VL levels seemed to positively predict the intention to be vaccinated only in the male sample, according to a univariable analysis, even after adjusting for socio-demographic factors.

Meta-analysis. In our meta-analysis, we found a statistically significant association between the intention to be vaccinated and overall VL score ($N = 3$, SMD = 0.51, 95% CI: 0.20 to 0.82, $I^2 = 89.0\%$), functional VL ($N = 7$, SMD = 0.34, 95% CI: 0.10–0.58, $I^2 = 94.0\%$), interactive VL ($N = 3$, SMD = 0.42, 95% CI: 0.17 to 0.68, $I^2 = 90.0\%$), critical VL ($N = 3$, SMD = 0.50, 95% CI: 0.38 to 0.61, $I^2 = 54.0\%$) and interactive/critical VL ($N = 5$, SMD = 0.42; 95% CI: 0.21 to 0.62, $I^2 = 84.0\%$) (Figure 2). Stratifying by vaccination, the intention to have the SARS-CoV-2 booster dose seemed to be associated with higher VL levels in all domains explored (functional VL: $N = 3$, SMD = 0.63, 95% CI: 0.45 to 0.81, $I^2 = 81.0\%$; interactive VL: $N = 3$, SMD = 0.42, 95% CI: 0.17 to 0.68, $I^2 = 90.0\%$; critical VL: $N = 3$, SMD = 0.50, 95% CI: 0.38 to 0.61, $I^2 = 54.0\%$), whereas for the primary vaccination cycle only higher interactive/critical VL appeared to positively influence vaccination intention ($N = 5$, SMD = 0.42, 95% CI: 0.21 to 0.62, $I^2 = 84.0\%$) (Figure 2(a), Supplementary Figure S1). Stratification by tool provided similar findings, with higher levels of VL in the functional, interactive and critical domains, as measured by the HLVa-IT tool, being associated with willingness to be vaccinated (functional VL: $N = 4$, SMD = 0.52, 95% CI: 0.28 to 0.75, $I^2 = 89.0\%$; interactive VL: $N = 3$, SMD = 0.42, 95% CI: 0.17 to 0.68, $I^2 = 90.0\%$; and critical VL: $N = 3$, SMD = 0.50, 95% CI: 0.38 to 0.61, $I^2 = 54.0\%$), whereas higher levels of interactive/critical VL, as detected by the COVID-19 VLS tool, seemed not to influence willingness to be vaccinated ($N = 2$, SMD = 0.35, 95% CI: −0.14 to 0.84, $I^2 = 95.0\%$) (Figure 2(b), Supplementary Figure S2). Stratifying by population found a statistically significant association between vaccination intention and a high VL score in all domains in the general population only (functional VL: $N = 5$, SMD = 0.42, 95% CI: 0.12 to 0.71, $I^2 = 96.0\%$; interactive VL: $N = 3$, SMD = 0.42, 95% CI: 0.17 to 0.68, $I^2 = 90.0\%$; critical VL: $N = 3$, SMD = 0.50, 95% CI: 0.38 to 0.61, $I^2 = 54.0\%$; and interactive/critical VL: $N = 2$, SMD = 0.59, 95% CI: 0.49 to 0.70, $I^2 = 0.0\%$) (Figure 2(c), Supplementary Figure S3). In a sensitivity analysis, when we used data from Biasio et al.[30] on influenza vaccination instead of SARS-CoV-2, the results did not change meaningfully for either the functional or the interactive/critical VL domains (functional VL: $N = 7$, SMD = 0.36; 95% CI: 0.14 to 0.58, $I^2 = 94.0\%$; interactive/critical VL: $N = 5$, SMD = 0.41; 95% CI: 0.22 to 0.59, $I^2 = 83.0\%$) (Figure 3, Supplementary Figure S4–6).

Association between VL and vaccination status

Systematic review. One study investigated HPV vaccine uptake in female university students, distinguishing two different ethnicities and using an ad hoc questionnaire to measure VL levels[40] (Table 3). A multivariable analysis was performed to evaluate the association between higher overall

Table 2. Association between vaccine literacy (VL) and vaccination intention.

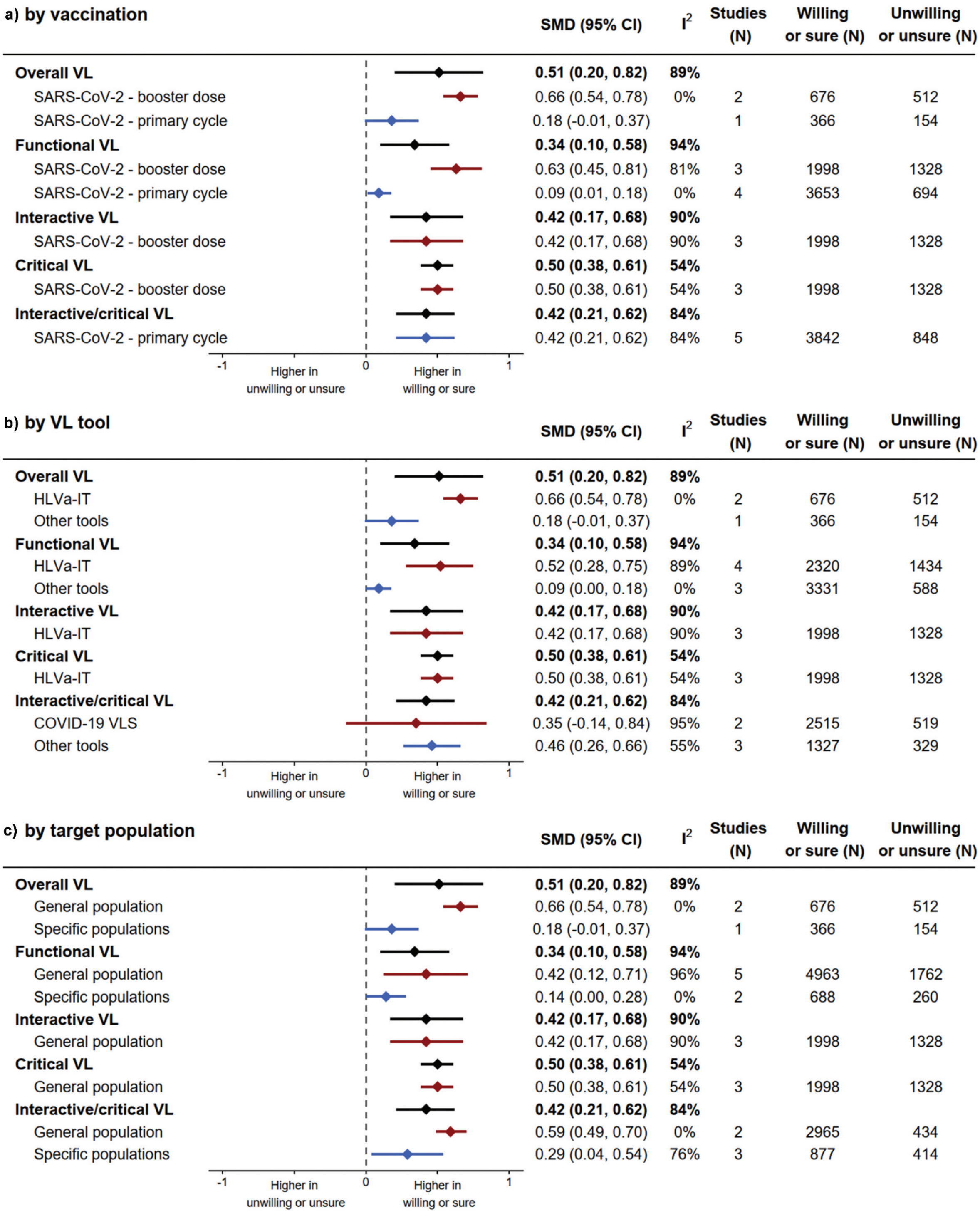
First author, year	VL: Measurement, coding	VL: Domains	Vaccination intention: Measurement	Vaccination intention: Coding	Statistical analysis	Main findings: Unadjusted analysis	Main findings: Adjusted analysis	Adjustment factors
SARS-CoV-2								
Biasio, 2020 (B) #	Adapted version of HLVa-IT, continuous	-Functional - Interactive/critical	One question on the intention to have COVID-19 vaccination	Two categories: – yes – no	Kruskal Wallis	Non-significant association between higher functional VL and the intention to be vaccinated ($p = .491$); significant association between higher interactive/critical VL and the intention to be vaccinated ($p < .001$)	NA	NA
Alshehry, 2021	Adapted version of HLVa-IT, continuous	- Interactive/critical	One question on the intention to have COVID-19 vaccination	Three categories: – no – not sure – yes	Multinomial logistic regression	NA	Non-significant association between higher interactive/critical VL and the intention to be vaccinated (β = −0.10)	COVID-19 risk perception and attitudes to COVID-19 vaccine
Krishnamurthy, 2021 #	Ad hoc questionnaire, continuous	– Interactive/critical	One question on the intention to have COVID-19 vaccination	Two categories: – yes – later/no	Not reported	Significant association between higher interactive/critical VL and the intention to be vaccinated ($p < .05$)	NA	NA
Yadete, 2021 #	HLVa-IT, continuous	- Functional - Interactive - Critical	One question on the intention to have booster dose	Two categories: – yes – no	t-Test	Significant association between higher functional, interactive, and critical VL and the intention to be vaccinated ($p < .001$)	NA	NA
Gendler, 2021 #	COVID-19 VLS (adapted from HLVa-IT), continuous	- Overall - Functional - Interactive/critical	Two questions on the willingness to vaccinate their children against COVID-19	Two categories: – very likely or somewhat likely – somewhat unlikely or definitely not likely	t-Test	Non-significant association between higher functional, interactive/critical, and overall VL and the intention to vaccinate their children ($p = .13$, $p = .31$ and $p = .06$)	NA	NA
Gusar, 2021	COVID-19 VLS (adapted from HLVa-IT), continuous	- Functional - Interactive/critical	One question on the intention to have COVID-19 vaccination	Two categories: – yes – no	t-Test	Significant association between higher functional and interactive/critical and the intention to be vaccinated (both $p < .01$)	NA	NA
Nath, 2021	COVID-19 VLS (adapted from HLVa-IT), continuous	- Overall	One question on the intention to have COVID-19 vaccination	Level of agreement: 0 = no; 10 = yes	Multiple linear regression	Non-significant association between higher overall VL and the intention to be vaccinated ($r = −0.05$)	Non-significant association between higher overall VL and the intention to be vaccinated (β = −0.02)	Age, gender, COVID-19 experience, conspiracy theory believing, influence of opinion leaders
Achrekar, 2022 #	HLVa-IT, continuous	- Overall	One question on the intention to have booster dose	Two categories: – yes – no/not sure	Hierarchical multiple regression	Significant association between higher functional, interactive, critical, and overall VL and the intention to be vaccinated ($p < .001$)	Subgroup analysis: non-significant association between higher overall VL and the intention to be vaccinated in hesitant individuals (β = −0.011)	Age, gender, education, income, marital status, region, living condition, empowerment
Batra, 2022 #	HLVa-IT, continuous	- Overall	One question on the intention to have booster dose	Two categories: – yes – no	Hierarchical multiple regression	Significant association between higher interactive ($p = .02$) functional, critical, and overall ($p < .001$) VL and the intention to be vaccinated	Subgroup analysis: significant association between higher overall VL and the intention to be vaccinated in hesitant individuals (β = −0.036)	Confidence, availability, accessibility, obtainability of the booster dose

(*Continued*)

Table 2. (Continued).

First author, year	VL: Measurement, coding	VL: Domains	Vaccination intention: Measurement	Vaccination intention: Coding	Statistical analysis	Main findings: Unadjusted analysis	Main findings: Adjusted analysis	Adjustment factors
Gutierrez, 2022 #	COVID-19 VLS (adapted from HLVa-IT), continuous	- Functional - Interactive/critical	One question on the intention to have COVID-19 vaccination	Two categories: – yes – no	Non-parametric test	Non-significant association between higher functional VL and the intention to be vaccinated ($p = .43$); significant association between interactive/critical VL and the intention to be vaccinated ($p < .01$)	NA	NA
Kittipimpanon, 2022	COVID-19 VLS (adapted from HLVa-IT), continuous	- Overall	One question on the intention to have COVID-19 vaccination	Three categories: – will not have – not sure – will have for sure	Point biserial correlation tests	Significant association between higher VL and the intention to be vaccinated ($p < .001$)	NA	NA
Correa-Rodriguez, 2022 #	HLVa-IT, continuous	– Functional – Interactive/critical	One question on the intention to have COVID-19 vaccination	Two categories: – yes – no	Non-parametric test	Non-significant association between higher functional and interactive/critical VL and the intention to be vaccinated ($p = .54$ and $p = .18$)	NA	NA
Li, 2022	Adapted version of HLVa-IT, continuous	– Overall – Functional – Interactive – Critical	One question on the intention to have COVID-19 vaccination	Two categories: – yes – no	Non-parametric test	Non-significant association between higher functional, interactive, critical and overall VL and the intention to be vaccinated ($p = .49$, $p = .80$, $p = .47$ and $p = .84$)	NA	NA
Influenza								
Biasio, 2020 (B) #	Adapted version of HLVa-IT, continuous	– Functional – Interactive/critical	One question on the intention to have the flu vaccination in the current year	Two categories: – yes – no	Kruskal Wallis	Significant association between higher functional and interactive/critical VL and the intention to be vaccinated ($p < .001$)	NA	NA
HPV								
Suzuki, 2022	Ad hoc questionnaire, continuous	– Overall	One question on the timing of having the HPV vaccination	Two categories: – from immediately to 3 years – no intention to have a vaccine	MLR	Non-significant association between higher overall VL and the intention to be vaccinated in female sample (OR = 1.47, 95% CI: 0.75–2.87) Significant association between higher overall VL and the intention to be vaccinated in male sample (OR = 2.35, 95% CI: 1.23–4.47)	NA Significant association between higher overall VL and the intention to be vaccinated in male sample (aOR = 2.12, 95% CI: 1.02–4.41)	Age, faculty, health habits

COVID-19: coronavirus disease 2019; HLVa-IT: Adult Vaccination Health Literacy in Italian; MLR: multivariable logistic regression. NA: not assessed; VL: vaccine literacy; β: beta coefficient.
#studies included in the meta-analysis.



a) by vaccination

	SMD (95% CI)	I^2	Studies (N)	Willing or sure (N)	Unwilling or unsure (N)
Overall VL	**0.51 (0.20, 0.82)**	**89%**			
SARS-CoV-2 - booster dose	0.66 (0.54, 0.78)	0%	2	676	512
SARS-CoV-2 - primary cycle	0.18 (-0.01, 0.37)		1	366	154
Functional VL	**0.34 (0.10, 0.58)**	**94%**			
SARS-CoV-2 - booster dose	0.63 (0.45, 0.81)	81%	3	1998	1328
SARS-CoV-2 - primary cycle	0.09 (0.01, 0.18)	0%	4	3653	694
Interactive VL	**0.42 (0.17, 0.68)**	**90%**			
SARS-CoV-2 - booster dose	0.42 (0.17, 0.68)	90%	3	1998	1328
Critical VL	**0.50 (0.38, 0.61)**	**54%**			
SARS-CoV-2 - booster dose	0.50 (0.38, 0.61)	54%	3	1998	1328
Interactive/critical VL	**0.42 (0.21, 0.62)**	**84%**			
SARS-CoV-2 - primary cycle	0.42 (0.21, 0.62)	84%	5	3842	848

b) by VL tool

	SMD (95% CI)	I^2	Studies (N)	Willing or sure (N)	Unwilling or unsure (N)
Overall VL	**0.51 (0.20, 0.82)**	**89%**			
HLVa-IT	0.66 (0.54, 0.78)	0%	2	676	512
Other tools	0.18 (-0.01, 0.37)		1	366	154
Functional VL	**0.34 (0.10, 0.58)**	**94%**			
HLVa-IT	0.52 (0.28, 0.75)	89%	4	2320	1434
Other tools	0.09 (0.00, 0.18)	0%	3	3331	588
Interactive VL	**0.42 (0.17, 0.68)**	**90%**			
HLVa-IT	0.42 (0.17, 0.68)	90%	3	1998	1328
Critical VL	**0.50 (0.38, 0.61)**	**54%**			
HLVa-IT	0.50 (0.38, 0.61)	54%	3	1998	1328
Interactive/critical VL	**0.42 (0.21, 0.62)**	**84%**			
COVID-19 VLS	0.35 (-0.14, 0.84)	95%	2	2515	519
Other tools	0.46 (0.26, 0.66)	55%	3	1327	329

c) by target population

	SMD (95% CI)	I^2	Studies (N)	Willing or sure (N)	Unwilling or unsure (N)
Overall VL	**0.51 (0.20, 0.82)**	**89%**			
General population	0.66 (0.54, 0.78)	0%	2	676	512
Specific populations	0.18 (-0.01, 0.37)		1	366	154
Functional VL	**0.34 (0.10, 0.58)**	**94%**			
General population	0.42 (0.12, 0.71)	96%	5	4963	1762
Specific populations	0.14 (0.00, 0.28)	0%	2	688	260
Interactive VL	**0.42 (0.17, 0.68)**	**90%**			
General population	0.42 (0.17, 0.68)	90%	3	1998	1328
Critical VL	**0.50 (0.38, 0.61)**	**54%**			
General population	0.50 (0.38, 0.61)	54%	3	1998	1328
Interactive/critical VL	**0.42 (0.21, 0.62)**	**84%**			
General population	0.59 (0.49, 0.70)	0%	2	2965	434
Specific populations	0.29 (0.04, 0.54)	76%	3	877	414

Figure 2. Stratified standardized mean difference (SMD) of vaccine literacy (VL) scores of individuals willing to be or sure about being vaccinated vs. unwilling or unsure individuals. CI: confidence interval. COVID-19 VLS: COVID-19 vaccine literacy scale. HLVa-IT: Adult vaccination health literacy in Italian.

VL and the self-reported completion of the vaccination protocol (three HPV doses). After adjustment for both sociodemographic and HPV-related factors, a significant association in both sub-groups was found.

Biasio et al. studied IPT vaccination using the HLVa-IT tool and found in a univariable analysis a significant association between the receipt of at least one vaccine (i.e., tetanus booster every 10 years, or pneumococcal and influenza vaccination for people aged ≥65 years) and higher VL scores in the functional domain only.[28]

Three studies considered influenza vaccination only.[30,43,45] They used different VL tools and analyzed the association between functional and/or interactive/critical VL with self-reported last-season vaccination status in a univariable analysis. The results were contrasting: higher VL levels (both functional and interactive/critical) were found to be significantly

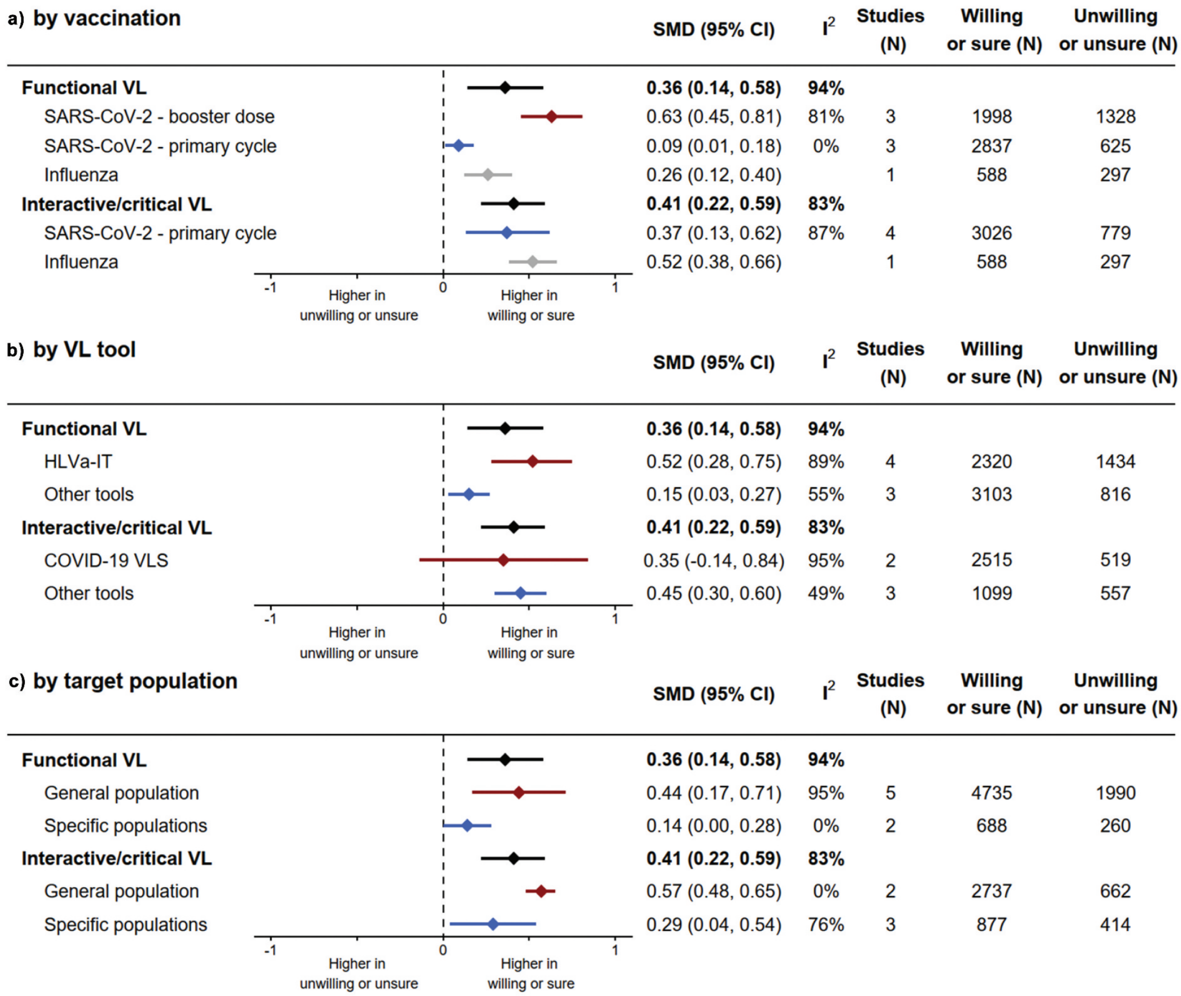


Figure 3. Sensitivity analysis of stratified standardized mean difference (SMD) of vaccine literacy (VL) scores of individuals willing to be or sure about being vaccinated vs. unwilling or unsure individuals. CI: confidence interval. COVID-19 VLS: COVID-19 vaccine literacy scale. HLVa-IT: Adult vaccination health literacy in Italian.

associated with previous flu vaccination uptake in the study by Biasio et al.,[30] but not in the study by Correa-Rodriguez et al.[45] Similarly, higher interactive/critical VL levels seemed not to predict the uptake of flu vaccination in the analysis conducted by Krishnamurty et al..[43]

Current vaccination status for SARS-CoV-2 was considered in four studies,[41,42,44,46] using the COVID-19 VLS tool in two cases[42,44] or an adapted version of the HLVa-IT tool in the other two cases[41,46] to evaluate VL levels. One study investigated only overall VL,[44] whereas the others reported data on at least two domains.[41,42,46] Vaccination status was always assessed by a self-reported question and the answers were dichotomized in all studies[41,42,44] but one, in which the outcome was divided into four groups in relation to the number of doses received.[46] The results were heterogenous: significantly higher functional and interactive/critical VL levels were found among vaccinated individuals in the only study in which adjusted estimates were provided.[41] Conversely, neither overall VL nor any VL domain seemed to be predictors of COVID-19 vaccine uptake in the univariable analyses conducted by Kittipimpanon et al. and Li et al., respectively,[44,46] while inconclusive findings were recorded in the study of Yilmaz et al., in which higher functional VL seemed to be positively associated with COVID-19 vaccination adherence in a univariable analysis, but not interactive/critical VL.[42]

Meta-analysis. In our meta-analysis, we found a nonstatistically significant association between being vaccinated and overall VL score ($N = 2$, SMD = 0.17, 95% CI: −0.01 to 0.35, $I^2 = 0.0\%$), or in relation to functional VL score ($N = 3$, SMD = 0.23, 95% CI: −0.11 to 0.57, $I^2 = 82.0\%$) but a significant association for interactive/critical VL score ($N = 4$, SMD = 0.22, 95% CI: 0.04 to 0.39, $I^2 = 52.0\%$) (Figure 4). After stratifying by vaccine, being vaccinated for SARS-CoV-2 was significantly associated with higher mean functional VL scores but not with interactive/critical VL values ($N = 1$, SMD = 0.60, 95% CI: 0.07 to 1.14; and $N = 1$, SMD = 0.25, 95% CI: −0.28 to 0.79, respectively), whereas being vaccinated for influenza was not associated with VL in any of the domains investigated (functional VL: $N = 2$, SMD = 0.13, 95% CI: −0.26 to 0.52, $I^2 = 89.0\%$; interactive/critical VL: $N = 3$, SMD = 0.21, 95% CI: 0.00 to 0.41, $I^2 = 68.0\%$) (Figure 4(a), Supplementary Figure 7). Stratification by VL tool provided similar results, with the COVID-19 VLS instrument showing significantly higher mean VL values among vaccinated people in the functional

Table 3. Association between vaccine literacy (VL) and vaccination status.

	VL		Vaccination status			Main findings		
First author, year	Measurement, coding	Domain	Measurement	Coding	Statistical analysis	Unadjusted analysis	Adjusted analysis	Adjustment factors
HPV								
Lee, 2015	Ad hoc questionnaire, continuous	- Overall	One SRQ on completion of three doses of HPV vaccination	Two categories: - completion of the vaccination protocol (3 doses) - no completion (0, 1 or 2 doses)	MLR	NA	Significant association between higher VL and the completion of HPV vaccination in both groups (AAPI: aOR = 1.99; White: aOR = 2.40)	Age, born non in US, father's education, HPV knowledge, medical visits, cancer history, number of sexual partners
Influenza + *Pneumococcus* + Tetanus								
Biasio, 2020 (A)	HLVa-IT, continuous	- Functional - Interactive - Critical	Three SRQs on vaccination status (tetanus booster every 10 years, pneumococcal and influenza for ≥65 years)	Two categories: - having had ≥ 1 vaccine - having had no vaccine	Spearman's rho and Kruskal Wallis	Significant association between higher functional VL and having had at least one vaccine ($p = .04$); non-significant association between higher interactive and critical VL and having had at least one vaccine ($p = .13$ and $p = .17$)	NA	NA
Influenza								
Biasio, 2020 (B) #	Adapted version of HLVa-IT, continuous	- Functional - Interactive/critical	One SRQ on last season's vaccination status	Two categories: - yes - no	Kruskal Wallis	Significant association between higher functional and interactive/critical VL and vaccination uptake ($p < .001$)	NA	NA
Krishnamurthy, 2021 #	Ad hoc questionnaire, continuous	- Interactive/critical	One SRQ on last season's vaccination status	Two categories: - yes - no	Not reported	Non-significant association between higher interactive/critical VL and vaccination uptake ($p > .05$)	NA	NA
Correa-Rodriguez, 2022 #	HLVa-IT, continuous	- Functional - Interactive/critical	One SRQ on last season's vaccination status	Two categories: - yes - no	Non-parametric test	Non-significant association between higher functional and interactive/critical VL and vaccination uptake ($p = .42$ and $p = .77$)	NA	NA
SARS-CoV-2								
Yilmaz, 2022 #	COVID-19 VLS (adapted from HLVa-IT), continuous	- Overall - Functional - Interactive/critical	One SRQ on vaccination status	Two categories: - yes - no	t-Test	Significant association between higher functional VL and vaccination uptake ($p = .03$); non-significant association between higher interactive/critical and overall VL and vaccination uptake ($p = .3$ and $p = .08$)	NA	NA

(*Continued*)

Table 3. (Continued).

First author, year	VL		Vaccination status		Statistical analysis	Main findings		Adjustment factors
	Measurement, coding	Domain	Measurement	Coding		Unadjusted analysis	Adjusted analysis	
Engelbrecht, 2022	Adapted version of HLVa-IT, continuous	- Functional - Interactive/critical	One SRQ on vaccination status	Two categories: - yes - no	MLR	Significant association between lower functional and interactive/critical VL and no vaccination uptake (OR = 1.74, 95% CI: 1.60–1.89) and OR = 1.90, 95% CI: 1.62–2.22)	Significant association between lower functional and interactive/critical VL and no vaccination uptake (aOR = 1.12, 95% CI: 1.01–1.23, and aOR = 1.35, 95% CI: 1.12–1.62)	Age, gender, race, education, employment, government's ability to roll out vaccines
Kittipimpanon, 2022 #	COVID-19 VLS (adapted from HLVa-IT), continuous	- Overall	One SRQ on vaccination status	Two categories: - yes - no	t-Test	Non-significant association between higher overall VL and vaccination uptake ($p = .13$)	NA	NA
Li, 2022	Adapted version of HLVa-IT, continuous	- Overall - Functional - Interactive - Critical	One SRQ on vaccination status	Four categories: - first injection - first and second injections - booster injections - full vaccination	Non-parametric test	Non-significant association between higher functional, interactive, critical, and overall VL and vaccination uptake ($p = .44$, $p = .19$, $p = .11$ and $p = .14$)	NA	NA

VL: vaccine literacy; NA: not assessed; AAPI: Asian American and Pacific Islander; OR: odds ratio; aOR: adjusted odds ratio; CI: confidence interval; SRQ: self-reported Question; HLVa-IT: Adult Vaccination Health Literacy in Italian. MLR: multivariable logistic regression.
#:studies included in the meta-analysis.

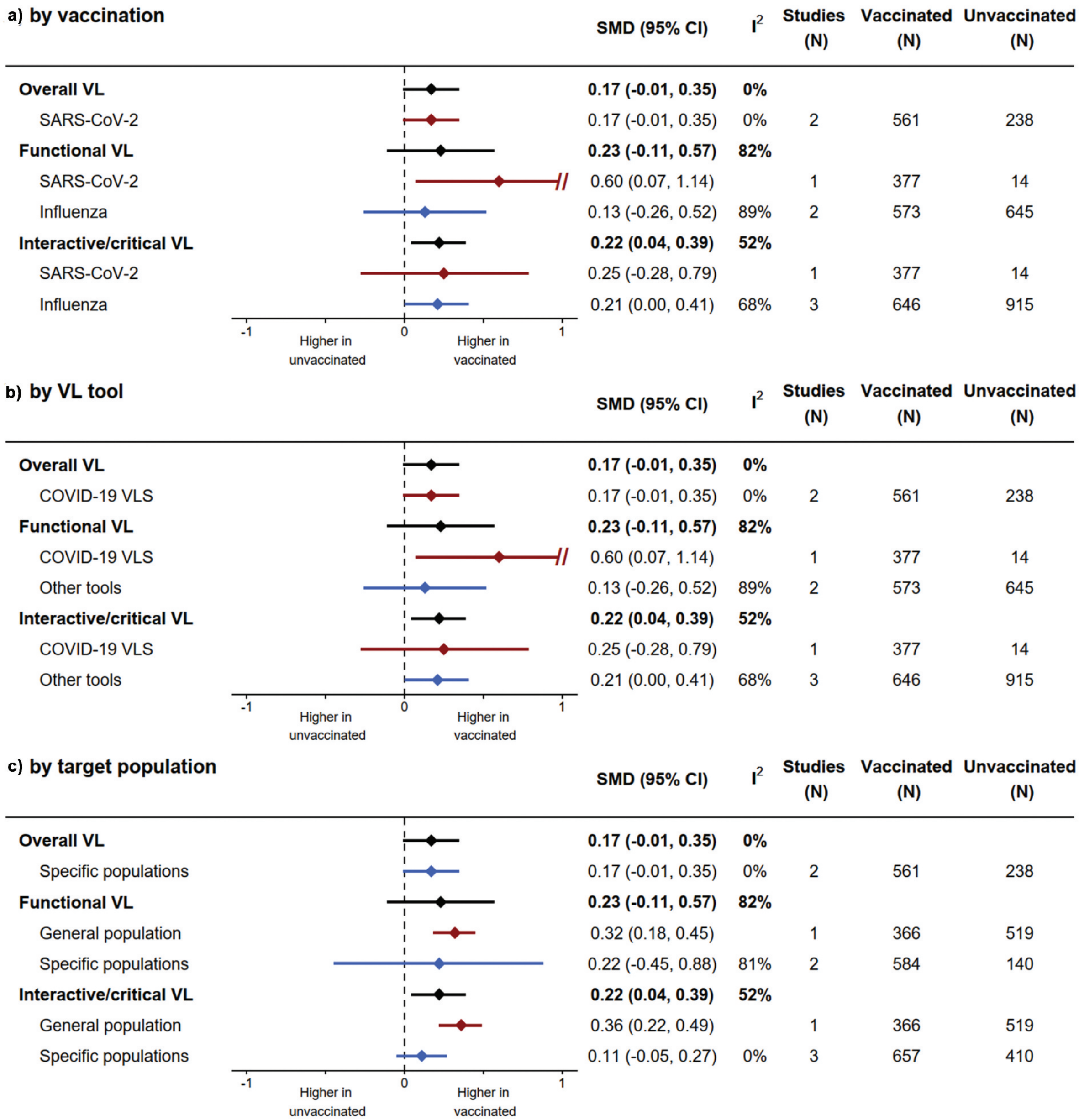


Figure 4. Stratified standardized mean difference (SMD) of vaccine literacy (VL) scores of vaccinated vs. unvaccinated individuals. CI: confidence interval. COVID-19 VLS: COVID-19 vaccine literacy scale.

domain only ($N = 1$, SMD = 0.60; 95% CI: 0.07 to 1.14) (Figure 4(b), Supplementary Figure 8). Lastly, stratification by target population indicated a statistically significant association between vaccination status and high functional and interactive/critical VL scores in the general population only ($N = 1$, SMD = 0.32, 95% CI: 0.18 to 0.45; and $N = 1$, SMD = 0.36, 95% CI: 0.22 to 0.49, respectively) (Figure 4(c), Supplementary Figure S9).

Discussion

Despite the apparent lack of conclusive evidence from the narrative synthesis of the results, the meta-analysis did find that VL is a strong predictor of vaccination intention, while its association with vaccination status is attenuated and barely significant. This finding is not unexpected,[21,22] given that vaccination intention may not always align with actual behavior.[27] Other factors, such as the availability and proximity of vaccination centers, the availability of an easy way to book vaccination appointments, or the various funding/reimbursement schemes can play a role in vaccination uptake.[47,48] In addition, despite all stratifications made, results were similar, probably because the stratification variables are correlated to some extent. As for the different domains investigated, it is well known that they reflect distinct abilities; thus, functional questions deal with language skills while the interactive and critical tasks involve problem-solving and decision-making processes.[28] Hence, although with different magnitudes, the strongest associations found between critical and interactive/critical VL and vaccination intention and status, may be attributable to the different capabilities targeted by the various domains, especially in relation to vaccination status where individuals must act to become vaccinated. However, it is also worth mentioning that all studies included in the critical domain analyzed the intention to have the SARS-CoV-2 booster dose, which showed a robust connection with VL, probably because individuals with a high level of VL are particularly aware of the importance of maintaining high levels of immunity over time. Conversely, the associations between the individual VL domains and vaccination status were all attenuated, with only the analysis with the greatest number of studies included reaching statistical significance. For this reason, more studies are needed to help establish the influence of VL on the actual uptake of vaccination, possibly using observational designs other than cross-sectional studies.[27] In addition, these studies should also better specify the definition of the outcome, which in some cases was unclear,[41,42,44] and confirm the vaccination status of their participants, allowing a more accurate measurement of the outcome.

Regarding the assessment of vaccination intention, a recent meta-analysis found that the number of possible answers to the question on COVID-19 vaccination intention influenced the pooled estimates of vaccine acceptance.[49] In our review, most studies analyzed vaccination intention using binary answers (i.e., yes or no), some of which isolated those who were sure about the vaccine from the individuals that were unsure or completely unwilling.[32,36,43] In the other cases, it was not specified whether there were only two possible answers or, alternatively, how the individuals that were uncertain about getting vaccinated were considered in the analyses.[30,33,35,38,45,46] While the first approach could overestimate levels of vaccination intention,[49] and potentially also affect the estimate of the association with VL, the effect of the second option depends on how the categories were collapsed. For this reason, being more explicit about how the outcome was assessed, as well as using validated tools that differentiate levels of vaccination intention, could improve its estimation and therefore also its association with VL.[31,34,44] As for the exposure assessment, even though a common definition and scope of VL are still under discussion,[22] we found that very few instruments were used to assess VL levels, with the most widely applied being the HLVa-IT tool. Given that VL and HL are strictly related,[20,27] but a clear correlation between HL and vaccine adherence has not always been found,[27] it is not surprising that the HLVa-IT tool was developed using scales previously used to assess HL levels.[28,50] However, even though the HLVa-IT instrument seemed to predict the outcomes of interest better than the other tools, consideration should be given to developing a commonly shared instrument that takes into account the differences among populations, including cultural beliefs[51] and the socio-demographic characteristics of the sample.[40,52] In this regard, recent efforts were made to provide a validated and internationally applicable tool for VL measurement with the development of HLS19-VAC.[19] Despite its scarce use in the literature to date, this instrument could provide a comprehensive measurement of the VL concept at European level and allow a better comparison of evidence.

Notably, we found a stronger association between VL and intention to be vaccinated among general population, even though most of the studies recruited individuals using the internet, a factor that may challenge the representativeness of these samples.[53] On the other hand, the few studies that focused on healthcare workers[43] or nursing students[31,42] found mixed evidence of an association between VL and both outcomes, suggesting that this category should be further investigated, especially considering the implications that this finding may have for both the subjects themselves and the patients they care for.[54] Further consideration could be given to the limited type of vaccines under assessment: almost all studies that quantified the intention to vaccinate focused on COVID-19 vaccination, probably because of the availability of new vaccines and their unknown impact on population attitudes and perceptions.[27] In this regard, the strong relationship between VL and the intention to have the COVID-19 booster has already been mentioned, even though this review did not arrive at a conclusive judgment on the role of VL in hesitant individuals.[37] By contrast, slightly more variety in the type of vaccine studied was found for vaccination status, but the findings were largely inconsistent for most vaccinations. Indeed, while some positive results were reported for both the intention to have the HPV vaccination[39] and the completion of the vaccination protocol,[40] we found that being vaccinated against influenza, SARS-CoV-2 or IPT did not seem to be strongly related to VL, in contrast to other individual factors, such as education level and income, that were found to be more involved in these vaccination decision-making processes. As previously discussed, a positive attitude toward vaccination may not always be followed by vaccination uptake,[27] particularly for routine immunizations, such as influenza or IPT. In such cases, a perception of low risk of infection, together with some aspects of vaccine convenience, including the quality of vaccination service and the time and place for getting the vaccination, could be neglected.[55] This may also explain why VL did not seem to be associated with flu vaccination status either in healthcare workers or in individuals with a chronic disease, two population subgroups that are usually health literate and well aware of the importance of vaccinations.[55,56]

This study has some strengths and limitations. First, we included articles that measured VL using both validated and non-validated tools, meaning that the reliability of some VL estimates may be sub-optimal. Second, since our focus was VL, we did not include studies that used ambiguous terms, such as 'literacy on vaccinations', with no clear definition. Third, since the high heterogeneity in the methods used and the few multivariable analyses carried out, we were only able to pool unadjusted estimates. Furthermore, since data was limited, some uncertainties remain, also considering that it was not possible to assess publication bias or conduct meta-regression analyses. The other limitations are mostly related to the primary studies included in this review. Given that our results are based on self-reported outcomes, social desirability bias could have affected the accuracy of our conclusions. Similarly, narrowly defined populations and questionable enrollment procedures may limit the generalizability of our findings. In addition, since all studies adopted a cross-sectional design, we could not draw any causal conclusions. For these reasons, further research should be conducted at both regional and national level, possibly using standardized methodologies in the design and analysis phases. However, to the best of our knowledge, this is the first study that provides a quantitative synthesis of the association between VL and vaccination behavior, considering separately the different VL domains and two aspects of the decision-making process (i.e., vaccination intention and status).

Conclusions

This review shows that VL strongly predicts vaccination intention, while its association with vaccination status is less marked and only marginally significant, meaning that additional factors may influence vaccination uptake. However, due to the paucity of available evidence, the heterogeneity of the methods employed, and the limitations of the studies included, it is crucial that further research be conducted to better clarify the role of VL in the vaccination decision-making process.

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Author contributions

CI and VB were responsible for conceptualization and project management, search design and execution. VB supervised the study. CI, JI, AS, ER and MB were responsible for screening, data extraction, quality assessment and interpretation. CI prepared the first draft. VB, CM and PV were responsible for revisions and approval to submit manuscript.

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